

HMA WGEO – Rapid Alert Form

Counterfeit or illegal product found in the illegal supply chain

Shaded area to be completed by the secretariat

Reference:		
Date: 12/07/2021	Time:	Initials:
Please complete sections 1 to 5 providing as much information as possible.		
1. REPORTING PERSON		
Name:	Position:	
Organisation:		
Address:		
Telephone No:	Ext:	
e-mail address:		
2. PRODUCT DETAILS		
Product name: MELATONIN 3 MG CÁPSULAS		
Manufacturer: Quality Supplements and Vitamins, Inc.		
Supplier: Life Extension Europe B.V., Frankfurtstraat 34-36, NL- 1175 RH Lijnden (Netherlands)		
Legal status: Banned <input type="checkbox"/> Counterfeit <input type="checkbox"/> Unlicensed <input checked="" type="checkbox"/> Stolen <input type="checkbox"/>		
Dosage form: Pills		
Strength: NA		
Batch / lot no: Unknown		
Is batch number genuine: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
If yes to the above, advise batch destination country: Not applicable		
Expiry date: Unknown		
Language of packaging: Spanish		
Date of discovery: 21/04/2021		
Details of discovery: After initial investigations carried out by Health authorities, the product was submitted to our Agency for containing 3 mg of melatonin.		

Analysed: YES ☐ NO ☒

If yes, result of analysis:

3. DISTRIBUTION METHOD

Internet: YES ☒ / NO ☐ (not exclusively through the internet)

Internet: Life Extension Europe

URL: www.lifeextensioneurope.com

Website address: -

Other details:-

Internet, advise full details:

www.lifeextensioneurope.com

Currency of payment: euros €

Has product reached patients/consumers? Yes

4. RISK TO PUBLIC HEALTH

Adverse reactions: YES ☒ / NO ☐

If yes, please advise details: Adverse reactions have not been notified. In any case, the presence of 3 mg of melatonin in a food supplement is considered an illegal medicinal product that pose a risk to public health.

Medical assessment details: Not applicable

5. NEED FOR PUBLICITY

Details as per original form

Are you making a public statement? YES ☐ / NO ☒

Are you issuing a press release? YES ☒ / NO ☐

Are you recalling product? YES ☒ / NO ☐

If yes to any of the above, when do you intend to take action?

Action was taken on 01st July 2021 (recall, note published on the AEMPS website¹).

6. DISSEMINATION

Are you content for this Rapid Alert to be shared outside WGEO membership?

YES ☒ / NO ☐ (please see below)

If yes, please specify which of the below you are content for this to be shared with (you may tick more than 1 box)

Law Enforcement ☒ Industry Security ☐ Trade Associations ☐

Traders ☐ Other ☐ Please specify _____

7. PHOTOGRAPH

If possible, please attach a photograph of the product. See below.

